K020310

Davlite Technologies

MAR 2 0 2002

Summary of Safety and Effectiveness

Trade Name:

The Davlite Microendoscope

Manufacturer Information:

Davlite Technologies
37 Kris Allen Drive
Holden, MA 01520

Contact: David A. McNally Phone: 508/829-4602 Fax: 508/829-5123 E-mail: davidmcn@ix.netcom.com

Establishment Registration Number: Form FDA 2891 submitted January 21, 2002 (copy next page)

FDA Device Classification:

Standard Product Nomenclature:	Laparoscope, General & Plastic Surgery
Device Description:	Endoscope and Accessories
Medical Specialty:	General & Plastic Surgery
Product Code:	GCJ
Device Class:	2
510(K) Exempt?	No
Regulation Number	876.1500

Intended Use and Product Description:

The Davlite Microendoscope will be labeled for the intended use of:

This device is to be used by a physician for viewing an interior cavity of the human body through either a natural opening or incision.

The Davlite Microendoscope is a semi-rigid fiberscope with a single use sheath and a re-useable (reposable) microendoscope. The microendoscope is provided and labeled non-sterile. The microendoscope must be sterilized prior to use. (See instructions for cleaning and sterilization).

Substantial Equivalence:

Establishment of equivalence is based on similarities of intended use, design, and materials, physical characteristics and geometry between the Davlite Microendoscope and Acueity Microendoscope (Viaduct) (K011189) and Solos Endoscope (K932987) among other marketed visualization products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

Davlite Technologies
Mr. David A. McNally
President
37 Kris Allen Drive
Holden, Massachusetts 01520

Re: K020310
Trade Name: Davlite Microendoscope
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 26, 2002
Received: January 29, 2002

Dear Mr. McNally:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Davlite Technologies

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: K020310

Device Name: Davlite Microendoscope

Indication for Use:

This device is to be used by a physician for viewing an interior cavity of the human body through either a natural opening or an incision.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (YES) NO or Over-the-Counter Use Yes No

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020310

(Division Sign-Off)_____

510(k) Number: K020310